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Filed: May 25, 2000

REMARKS

Claims 1-21 and renumbered Claims 34-39 remain presented for examination. No new matter has been added, and no new amendments have been made in this response. Applicants wish to thank the Examiner for his examination of the pending claims, and for the withdrawal of the previous rejections of Claims 1-21 under 35 U.S.C. § 112; Claims 1-3, 6, and 16 under 35 U.S.C. § 102(e); and Claims 1-21 under 35 U.S.C. § 103(a).

Rejection under 35 U.S.C. § 112, second paragraph

The Examiner rejected Claims 1-21 and 34-39 under 35 U.S.C. § 112, second paragraph as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. The Examiner alleges that the recitation of “substantially free of added raffinose and added enzymes” renders the claims vague and indefinite.

Regarding the term “substantially,” Applicants assert that this term, as used in Claims 1 and 16 of the present invention, is a definite term (*see In re Mattison*, 509 F.2d 563, 184 USPQ 484 (CCPA 1975), *Andrew Corp. v. Gabriel Electronics*, 847 F.2d 819, 6 USPQ2d 2010 (Fed. Cir. 1988), and MPEP 2173(b).D).

Further, the examiner appears to object to the words “substantially free...” as being vague and indefinite. However, the following list is just a small sample of U.S. granted biotechnology patents that have been allowed with the limitation “substantially free” in the claims:

US06416999; US06458573; US06451563; US06428824; US6410062; US06416947; USRE037741; US06525102; US06426074; US06485755; US06355239; US06150316; US05516533; and US05275826.

Because the claim limitation “substantially free ...” is found in these and many other granted patents, the Applicants assert that the language is not vague or indefinite, and thus the rejection of the terms “substantially free...” in the claims should be withdrawn. “The PTO’s interpretation of claim terms should not be so broad that it conflicts with the meaning given to

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identical terms in other patents from analogous art." *In re Cortright*, 165 F.3d 1353, 1358 (Fed. Cir. 1999).

Further, examples of a "substantial" amount of raffinose can be found in the cited prior art. For example, Pancholi et al. (6,190,659) discloses the use of 30% raffinose. This would be considered by a person of ordinary skill in the art to be a "substantial amount." The method of the present invention, in contrast, does not contemplate the addition of large amounts of raffinose. However, if a small percentage of raffinose were to be present in the extract, for example, as a contaminant, this would not alter the invention.

Additionally, the cited prior art discloses the amount of enzyme that would be considered "substantial." Pancholi discloses a muralytic enzyme mutanolysin at a concentration of 20 μ g/ml. Matsuzaki discloses the use of 670 units of achromidase per ml of bacterial culture. Link (5,185,321; submitted herewith and related to EPO 432 490 A2; submitted December 5, 2002) discloses the addition of 4% lysozyme to a *Lactobacillus* culture. These are examples of "substantial" amounts of enzyme that would be appreciated as such by persons of skill in the art. In contrast, in the present invention, the invention works without the need for added enzymes. However, if a small amount of enzyme is present, for example, as a contaminant, this should not alter the invention.

Considering all of the above, the Applicants request withdrawal of the rejection of claims 1-21 and 34-39 under 35 U.S.C. § 112, second paragraph.

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Rejection under 35 U.S.C. § 112, first paragraph

The Examiner rejected Claims 1-21 and 34-39 under 35 U.S.C. § 112, first paragraph, as allegedly being new matter. The Examiner alleges that while the claims have been amended to include the limitation “substantially free of raffinose and added enzymes,” the Applicants have not provided clear support for the newly added limitation.

The requirements of the first paragraph of 35 U.S.C. §112 are satisfied by the specification as filed with respect to the use of the claim limitation “substantially free of raffinose and added enzymes.” Applicants note that, as decided in *Ex parte Parks (Bd Pat App & Inter, 30 U.S.P.Q. 2d 1234 (1993))*, the requirements of the first paragraph of 35 U.S.C. §112 are satisfied if the originally-filed disclosure would have conveyed to one having ordinary skill in the art that Applicants had possession of the claimed subject matter, even if a particular concept was not literally stated in the originally filed application. In particular, in *Ex parte Parks* the Board of Patent Appeals and Interferences found that the written description requirement was satisfied with respect to a claim limitation specifying that the claimed process was performed “in the absence of a catalyst” despite the fact that those exact words did not appear in the specification as filed because the originally filed specification conveyed to those skilled in the art that Applicants had possession of the concept of performing the method in the absence of a catalyst.

Support for the limitation “substantially free of raffinose” can be found throughout the specification, since there is no teaching or suggestion that raffinose is added to the acid treatment solution, anywhere in the specification. Similarly, support for the limitation “substantially free of added enzymes” is also found throughout the specification, as nowhere in the specification is the addition of enzymes to the mixture suggested or taught.

One of the advantages of the methods of the invention, clearly explained throughout the specification, is that the methods work without the need for added enzymes. For example, the specification clearly describes that one of the benefits of the invention is that enzymes, such as the extremely expensive “achromidase” are not needed: “such an extract is extremely expensive to prepare because of the treatment of peptidoglycan with the specific Achromopeptidase enzyme from *Achromobacter*. Of interest is a peptidoglycan extract which has comparable anti-tumor

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effects, but is easier and less expensive to produce" (page 2, lines 15 – 19). Thus, the use of enzymes is mentioned, but only as a comparison to show how the extract of the present invention can be prepared more easily with less expense than extracts that utilize enzymes.

Further, Example 1 provides a general method of production of the extract (page 4, line 20 to page 5, line 18). In this example, the bacterial pellet is mixed with deionized water and glacial acetic acid. There is no teaching or suggestion of adding raffinose or enzymes. Another example is provided in Example 2, where a crude extract is prepared. In this example, the pellet was mixed with water and glacial acetic acid (page 5, lines 25-26). Again, there is no teaching or suggestion of adding raffinose and no mention of adding enzymes. Nor is there such a suggestion anywhere else in the specification.

As mentioned above, as decided in *Ex parte Parks (Bd Pat App & Inter, 30 U.S.P.Q. 2d 1234 (1993))*, the requirements of the first paragraph of 35 U.S.C. §112 are satisfied if the originally-filed disclosure would have conveyed to one having ordinary skill in the art that Applicants had possession of the claimed subject matter, even if a particular concept was not literally stated in the originally filed application. Thus, the Applicants request the withdrawal of the rejection of Claims 1-21 and 34-39 under 35 U.S.C. § 112, first paragraph, based on the limitation "substantially free of raffinose and added enzymes."

Claims 1-21 and 34-39 are further rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors had possession of the invention at the time the application was filed. Specifically, the Examiner issued a new matter rejection, alleging that the claim amendment to include the limitation "pH of less than 6.8" is not clearly supported in the specification. Additionally, the examiner rejected Claims 34-39 alleging that the limitations citing a pH of less than 6.0, 5.0, etc. are not clearly supported in the specification.

However, one of skill in the art, upon reading the specification, would clearly understand that an "acid treatment solution" of the present invention can have a full range of pH possibilities

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that would be effective to create an immune-stimulating composition. One of skill in the art would know that an "acid treatment solution" could easily have a pH of, for example, 6.0, or 5.0, or 4.0, etc. Examples 1 and 2 of the specification cite a pH of 2.0, but clearly other pH levels (either higher or lower) are possible and would be contemplated by one of skill in the art. As long as an immune-stimulating composition is achieved, the exact pH of the "acid treatment solution" can vary throughout a wide range.

Considering all of the above, the Applicants request withdrawal of the rejection of claims 1-21 and 34-39 under 35 U.S.C. § 112, first paragraph.

Applicants have endeavored to address all of the Examiner's concerns as expressed in the outstanding Office Action. Accordingly, amendments to the claims, the reasons therefor, and arguments in support of the patentability of the pending claim set are presented above. Any claim amendments which are not specifically discussed in the above remarks are made in order to improve the clarity of claim language, to correct grammatical mistakes or ambiguities, and to otherwise improve the capacity of the claims to particularly and distinctly point out the invention to those of skill in the art. In light of the above amendments and remarks, reconsideration and withdrawal of the outstanding rejections is specifically requested.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410. If the Examiner finds any remaining impediment to the prompt allowance of these claims that could be clarified with a telephone conference, the Examiner is respectfully requested to initiate the same with the undersigned.

Respectfully submitted,

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